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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte CHRISTOPHER G. TAYLOR, and YONG HUANG

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Appeal 2009-010547
Application 09/386,605
Technology Center 1600

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Oral Hearing Held: April 14, 2010

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Before TONI R. SCHEINER, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, Administrative Patent Judges

ON BEHALF OF THE APPELLANT:

ROBERT E. HANSON, PH.D.
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The above-entitled matter came on for hearing on Wednesday, April 14, 2010, commencing at 9:05 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Ashorethea Cleveland, Notary Public.

DR. HANSON: My name is Rob Hanson with Sonnenschein Nath & Rosenthal and this is David Foster who is also with our firm. He's going to be observing.

JUDGE SCHEINER: You came in together. That's why I wasn't sure if you were an observer from the public. It is a public hearing; so, that's okay. Either way, it's okay.

DR. HANSON: Yes, Your Honor.

JUDGE SCHEINER: All right. Whenever you would like to get started.

DR. HANSON: Okay. Thank you. May it please the Board. Good morning and I appreciate your time today.

I think you're aware that there's a single issue on appeal and that's the obviousness rejection of claims one and eight to eleven over Trulson, Simpson and Savka.

I want to make two points today and I think each of which will show why the rejection should be reversed.

When we go through the steps and look at the steps, you will see why our claim method is different, and our claim method results in chimeric plants as claimed, which I will discuss in a minute, while the cited art does not; and secondly, the record is completely devoid of any reason why somebody would even try to use this method, and I will explain that, as well.

JUDGE LEBOVITZ: It looked to us that the claim method was the same thing as what Trulson was doing and that is what we were having trouble discerning.

DR. HANSON: And if you want, we can start with that. I will walk through the differences. So, that was a key difference.

So, the key distinction here is that Trulson was trying to make clones. Trulson was trying to make a completely transgenic plant, and this is acknowledged by the Examiner in the Examiner's Answer. The Examiner says in fact, Trulson would have thrown out our plants. They would have thrown out the chimeric plants.

If you look at a plant, all of the reproductive parts of a plant are in the aerial portions; so, in the stems, leaves, et cetera. It's all above ground.

Transgenic roots will get you nowhere for passing it to the next generation.

So, Trulson was -- the point was to make transgenic plants so you could sell the seed to a farmer.

So, the Trulson method has to have transgenic, above-ground portions.

Then the question would be: Why doesn't Trulson result in chimeric plants as alleged by the Examiner? If you have a copy of Trulson, I'll --

JUDGE LEBOVITZ: On the flipside, why doesn't your claim result in what Trulson made?

DR. HANSON: Okay. First, I will show you why our method does not result in clones. Okay. So, if you have claim one in front of you, if

you'll look at our method, our method you can see in the preamble, producing a transformed dicotylsis, chimeric dicotylsis, dicotyledonous plant.

So, step one is obtaining a stem or explant that has a cut below the cotyledon, and then you transform that in a sense wherein the cut end is contacted with Agrobacterium rhizogenes, and this is the distinction and you can see it.

The next step is culturing the transformed explant and root-initiating media.

So, you have an explant. This is a portion of a hypocotyl which is like a stem, and then you contact the cut end, at the bottom, with the Agrobacterium rhizogones and then you put that in root-initiating media and the roots grow and grow directly from that, from that cut site. So, this is the above portion.

If you read the Specification, one of the nice things about this is, you can leave the cotyledon, the leaves on. If you look at like a bean seed, the energy is in the mature cotyledons. The root will grow out and they will be transgenic. So, now you have transgenic roots and you have wild-type stems without the need to do all this tissue culture.

You can see a significant part of this: So, you grow the roots from that and then you can see this next step is transferring. You can transfer it directly to soil or hydroponic environment.

JUDGE SCHEINER: You only find the organism in the extending root? It doesn't get into the cells above the cut?

DR. HANSON: Yes. Right. So, the method results in the chimeric plant because those tissues are already there; and so, unless it was invasive, like a tumor cell or something where it could --

JUDGE SCHEINER: Okay.

JUDGE LEBOVITZ: What we're really saying is that the exogenic DNA is expressed only in the roots --

DR. HANSON: Right.

JUDGE PRATS: How do you know that it doesn't infiltrate into the hypocotyl material above the cut and transform those cells?

DR. HANSON: There's no logical reason to think it would. I mean, the cells have to be attached. I mean, it's not like a, you know --

JUDGE PRATS: Well, if you dip it in, doesn't the DNA or the bacteria containing the DNA get absorbed into the cells?

DR. HANSON: I think that one important thing is, the agrobacterium requires a cut and you probably know agrobacterium. There's a chemical cascade. In the wild, that's how agrobacterium works. It's all these pseudosyringenes -- syringones. It's been a long time since graduate school. But all these different chemicals and that's why there has to be the cut, and that's the key.

So, when there's a wound site, that's when the for example RI plasma of agrobacterium. That's when it's activated based on all these chemicals produced by the --

JUDGE SCHEINER: I think what's confusing us is that the hypocotyl becomes -- I mean, there's a cut and a cut has two sides, one on the side that's going to become the roots. Does it cut all the way through so that you have a cut surface entirely and the roots will grow from that, or is it

a partial cut in the hypocotyl so that -- I mean, what's different about the top and bottom?

DR. HANSON: Yeah. If you look at our working examples, you will see they got rid of the parts above.

JUDGE SCHEINER: Altogether?

DR. HANSON: You don't need the parts above the cut. You want the cotyledons. You don't need the part above. You cut it. That's not what you cut. So, you contact the bottom side where the roots would be. That's what contacted and that's what's inoculated with the agrobacterium and that's where the roots are --

JUDGE PRATS: And those cells are the cells that take up the DNA and then --

DR. HANSON: Correct.

JUDGE SCHEINER: So, nothing that's going to be differentiated from the stem --

JUDGE PRATS: Differentiated to the root.

DR. HANSON: Correct.

JUDGE SCHEINER: -- will take up the DNA?

DR. HANSON: Correct. Those are the cells that are wounded and those are the cells that are contacted with the agrobacterium.

JUDGE SCHEINER: Trulson inverted the -- Trulson cut hypocotyl, as well, and inoculated it; right?

DR. HANSON: Right.

JUDGE SCHEINER: But inverted the cut?

DR. HANSON: Right. So, if you're comfortable with why our method would produce a chimera, then do you want me to explain why Trulson does not result in a chimeric?

JUDGE SCHEINER: Sure.

DR. HANSON: Okay. So, Trulson. There are two things we want to look at but I'll talk about the methodology first and then maybe I can talk about what the Examiner alleges. Like if you look at Table A, there's all these plants that were regenerated that were allegedly chimeric. I'm going to show why those weren't chimeric. I think the best place to look is page six, if you look at lines one through 15.

You've probably seen in the briefings these Series A and Series B plants. So, this is what it's all about. These are the plants that are asserted to be chimeric.

And if you look at the methodology, the methodology by which Series A and Series B were produced are in lines one through 15 on page six. And if you look there.

So, essentially, they took a hypocotyl. They cultured that. And then if you look at line four, it says in a first series of tests, Series A roots five to ten millimeters in length produced on the inoculated surfaces were excised. Okay. So, this is the key, the key distinction. The roots were excised and placed on a medium. So, then they're medium for two to three weeks.

Series B was the same thing. The difference was that in Series B they had kanamycin, selected agent. But there, also, they excised the roots and then they cultured those roots and then embryoids appeared on the

surface of the root, and then they detached that, and then they cultured that and turned that into a plant.

So, they have two different rounds of selection; and I think the best illustration of the difference with this and why that wouldn't be expected to result in a chimeric like ours --

JUDGE PRATS: So, in Trulson's method you're saying that the embryoid arises from the transformed roots?

DR. HANSON: Right. I mean, it's a clonal tissue --

JUDGE PRATS: And then you take the embryoid and culture that?

DR. HANSON: Exactly.

JUDGE PRATS: But in your method, you leave material there. So, you don't recreate an embryoid?

DR. HANSON: Right. So, you're not taking clonal tissues. I think the Savka reference illustrates this point. I think that concept is pretty straightforward.

But if you look at the Savka reference, if you have that in front of you, on page 506. So, if you have the Savka reference, page 506 and the first paragraph on the left-hand column. It's just talking about their methodology. It says: "When root primordia had elongated to approximately two centimeters the entire hypocotyl or cotyledon was dissected." Then there's this next sentence talking about some roots didn't grow. So, they're elongating roots. They're growing roots. And then the important sentence here. It says: "After one week, clonal lines were established by subculturing single roots."

So, here they're selecting single roots and they're considering that to develop a clonal line.

Now, if you look at the Trulson method, they do two different selections. They excise the root and that's a first selection; and then they pick the embryoids. So, they have two different steps, each of which you would expect to produce a clone which is consistent with the purpose.

The Examiner, you know, said on the record. The Examiner said that Trulson did more than make chimeras. Their whole goal was to make a clonal line which makes sense because they had to go through these steps. I mean, they had to do the tissue culture; but otherwise, that's how you would want to develop --

JUDGE PRATS: So, can you point to the claim and show us where in the claim Trulson's method of clonally deriving the plant is excluded?

DR. HANSON: Yes, Your Honor, if you have the claim in front of you. So, in claim one and this first step, we have the hypocotyl. So, the hypocotyl has the cut end; and then in Step B, the agrobacterium rhizogenes is contacted on the cut end. So, there's your inoculation. And then the significant part is this next step requires culturing the explant in a root-initiating media. So, you're taking the explant and you're culturing roots from the explant. So, there's no incision. You're culturing the roots from the explant in a root-initiating media. So, you're putting the explant in a root-initiating media. Trulson would never put an explant in a root-initiating media. They would excise a portion of the root and would put that in there but not the explant.

And so, that's transferred. So, this is transferred. You take straight from this rooted explant and then you put that in a soil or hydroponic environment.

If you're doing more culturing, it would say -- taking that tissue culture which would be -- under the prior art, you would have to do tissue culture.

JUDGE PRATS: So, the contrast is, you're regenerating? Trulson was regenerating essentially the entire plant from transformed cells whereas you all are just taking the bottom of the plant, if you will, and transforming that and growing the top from what was already there which was untransformed; right?

DR. HANSON: I think that's correct, Your Honor. I think we'll explain the Specification. That's a benefit. You can use the energy that's, for example, in the cotyledons.

As you can imagine, what Trulson went through is a lot of work to take basically a little piece of root and then to tissue culture that and then select embryoids and then regenerate a whole, entire plant from that. That has some problems.

JUDGE SCHEINER: Okay. Do you have anything further? I think we understand the issue.

DR. HANSON: Okay. Very good. And Simpson and Savka. They don't add anything on that, I think, if you're comfortable with that. I don't want to muck things up.

JUDGE SCHEINER: I think we understand.

DR. HANSON: Sometimes you need to just be quiet.

JUDGE SCHEINER: All right. I think it was Trulson that we really needed some enlightenment on.

DR. HANSON: Okay. Well, if there is nothing else I can answer.

JUDGE SCHEINER: I don't have anything further.

DR. HANSON: Okay. Well, thank you very much, Your Honors. I appreciate it. Have a good day.

JUDGE SCHEINER: Thank you very much.

Whereupon, at approximately 9:18 a.m., the proceedings were concluded.